L5 Overview of ISO/IEC 17025:2017 Standard

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International Atomic Energy Agency

Objectives

In this lecture we will discuss overview of ISO/IEC 17025:2017 to create awareness of this standard.

ISO/IEC 17025:2017

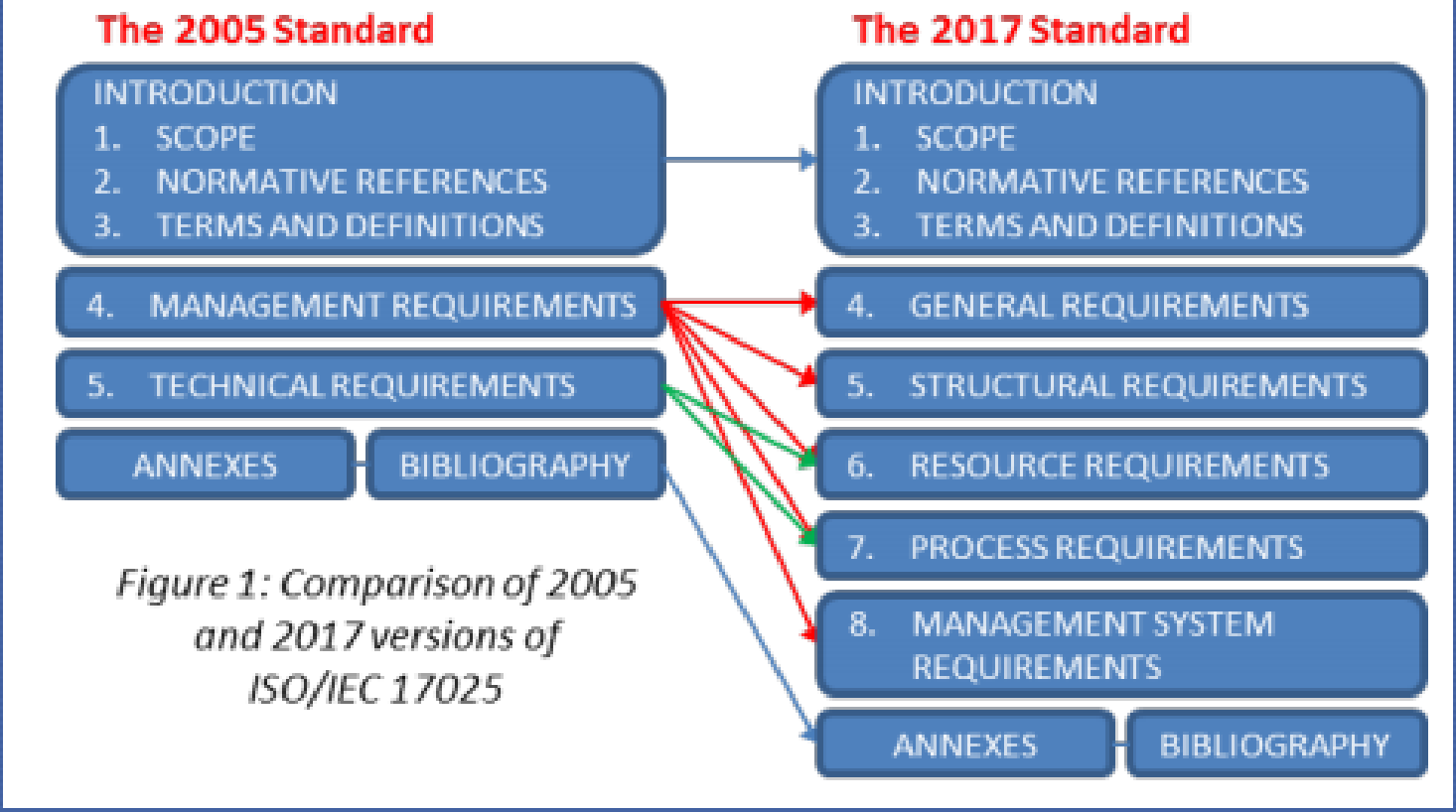

Figure 1: Comparison of 2005 and 2017 versions of ISO/IEC 17025

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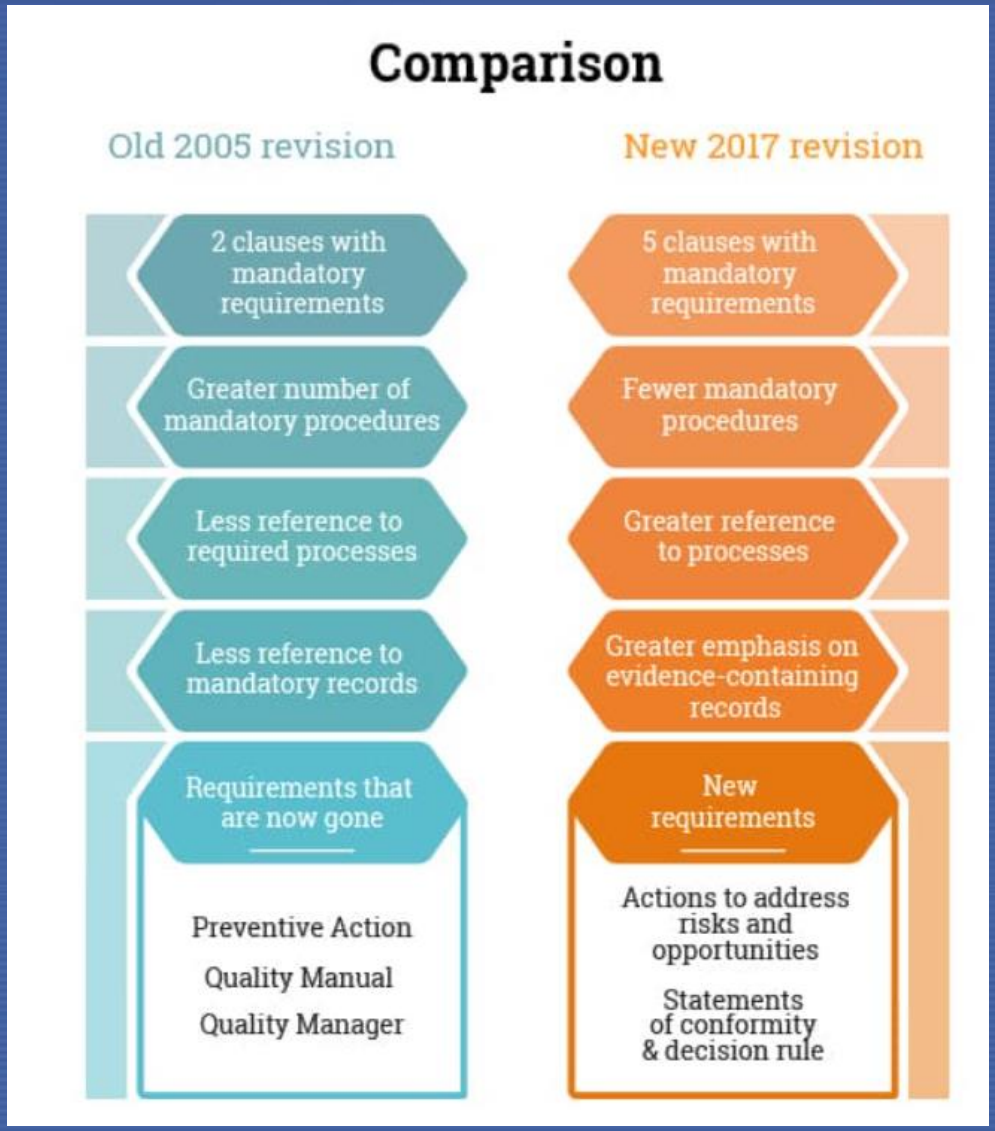
Old versus new standard



Message from ISO/IEC 17025:2017

Message i

Say what you do; Do what you say; Record what you do, Check the difference, Act on the difference

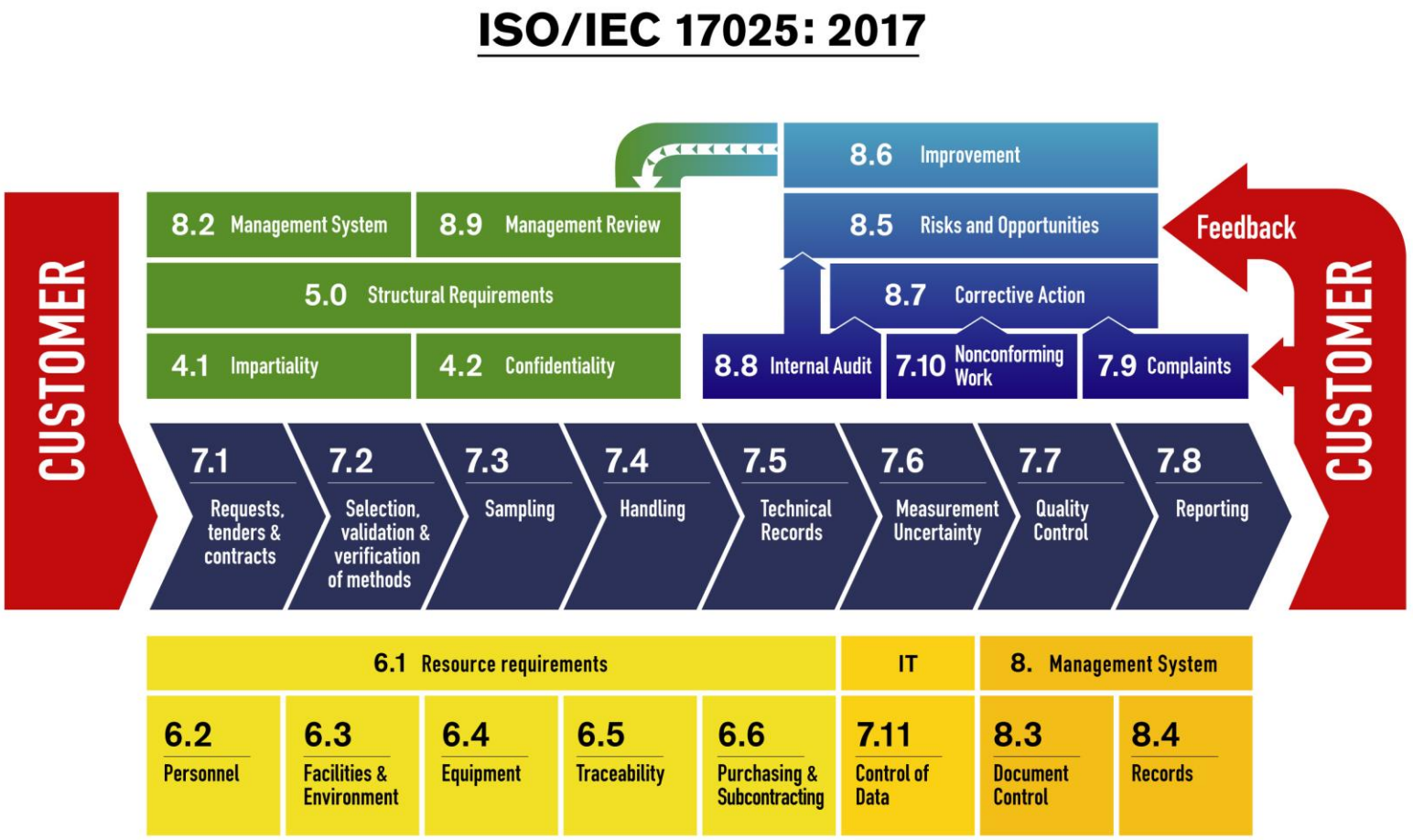
Message ii

Do the right thing right the first time and every time to achieve consistent quality

Message iii

Continual improvement is the way of life

Structure of ISO/IEC 17025.2017



Important definitions

- The terminology was updated, which means that the ISO/IEC 17025:2017 standard covers the newest ISO/IEC terminology and the changes that have been included in the International Vocabulary of Metrology (VIM).
- Under the section terms and definitions of the ISO/IEC 17025:2017 standard, the term “laboratory” has been added. This term refers to the bodies that perform one or more of the following activities such as testing, calibration, and/or sampling, associated with subsequent testing or calibration. Sampling is introduced as stand-alone laboratory activity along with subsequent testing or calibration
- “Decision rule” as defined term is introduced. When issuing a statement of conformity, the laboratory has to apply certain criteria in order to decide whether or not the results fulfil the specified requirements, e.g. pass or fail a test. Such decision rules have to take into account the measurement uncertainty of the results as well as the risk of false statement

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“Risk Based Thinking”

- Requirements are weighted according to the risk of nonfulfillment and the potential effects. In this context, the formerly required “preventive action” is now part of this risk-based approach.
- Similar to the evaluation of impact regarding the quality of work and validity of results, decisions and operations of the laboratory have to be guided by the potential influence on the intended effect. The laboratory is responsible for deciding which risks and opportunities associated with its policies and procedures need to be addressed. This applies particularly to
  - risks to the laboratory’s impartiality (see 4.1.4);
  - risks caused by invalid methods (see 7.2)
  - risks of false accept or false reject when providing statements of conformity (see 7.8.6);
  - risks caused by nonconforming work (see 7.10);
  - risks becoming apparent during corrective actions (see 8.7);
  - risks to the effectiveness of the management system and risks of potential failure of the laboratory activities (see 8.5);
  - risks identified and subjected to management reviews (see 8.9).

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1. Scope

- ISO/IEC 17025 specifies the general requirements for the competence, impartiality and consistent operation of laboratories

- It is applicable to all organizations, regardless of the number of personnel, performing laboratory activities, regardless of the number of personnel.

- Laboratory customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others use it in confirming or recognizing the competence of laboratories.

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2. Normative references

- ISO/IEC Guide 99 International vocabulary of metrology — Basic and general concepts and associated terms (VIM)

- ISO/IEC 17000, Conformity assessment — Vocabulary and general principles

3. Terms and definitions

3.1 Impartiality

Presence of objectivity (Freedom from conflict of interest)

3.2 Complaint

Expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected

3.3 Inter laboratory comparison

Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

3.4 Intra-laboratory comparison

Organization performance and evaluation of measurements or tests on the same or similar items, within the same laboratory, in accordance with predetermined conditions

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3 Terms and definitions

3.5 Proficiency testing

Evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons

3.6 Laboratory

Body that performs one or more of the following activities:

- Calibration
- Testing
- Sampling, associated with subsequent calibration or testing

3.7 Decision rule

Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

3 Terms and definitions

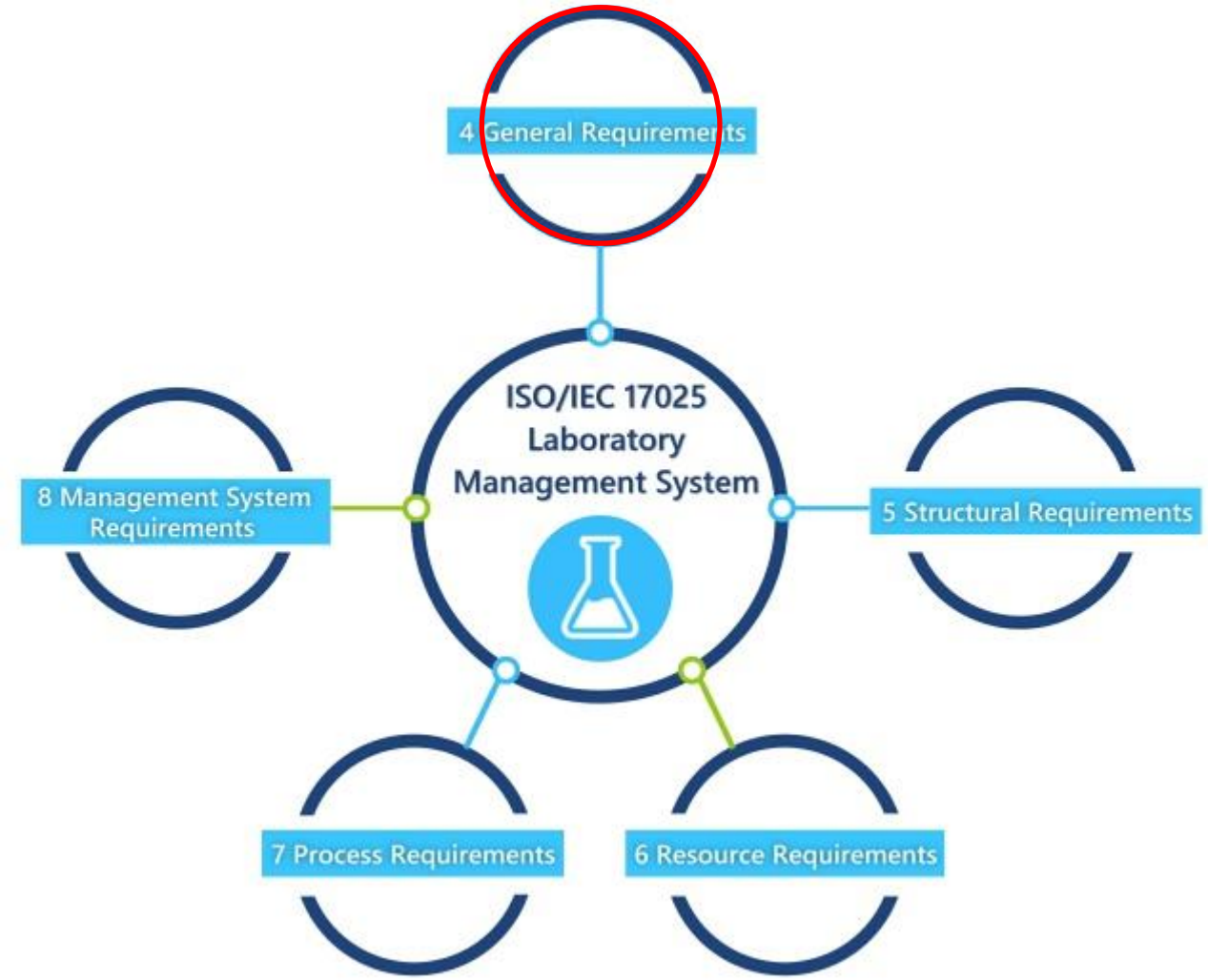
3.8 Verification

Provision of objective evidence that a given item fulfils specified requirements.

3.9 Validation

Verification, where the specified requirements are adequate for an intended use.

4. General requirements



The different sections

- Section 4: General Requirements. This clause includes impartiality and confidentiality, whereby the laboratory activities are to take into account impartiality and safeguard the confidentiality of all the information obtained during the execution of laboratory activities. Impartiality implies that the laboratory will not allow commercial, financial, or other pressures to compromise the quality of results. Internal issues, personal relationships, or other conflicts of interest are addressed and resolved. Confidentially requires the laboratory to keep all results and information private and secure.

4.1 Impartiality

4.1.1 Safeguard impartiality and undertake laboratory activities (structured, managed and impartial way)

4.1.2 Management commitment for impartiality

4.1.3 Responsible for impartiality and not allow commercial, financial or other pressures.

4.1.4 Identify risk on an on going basis to impartiality (Include risk arises from activities, relationships and personnel)

4.1.5 If risk is identified then demonstrate to eliminate or minimize risk to impartiality

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4.2 Confidentiality

4.2.1 Proprietary information to be kept confidential as per legally enforced commitment like contract terms

4.2.2 Inform customer/ concerned individual to release confidential information if required by law or authorized by contractual arrangement

4.2.3 Do not share information to customer if customer related information received from other sources unless agreed by source

4.2.4 All personnel including contractors and individual acting on the laboratory's behalf to keep information confidential for laboratory activities except by law

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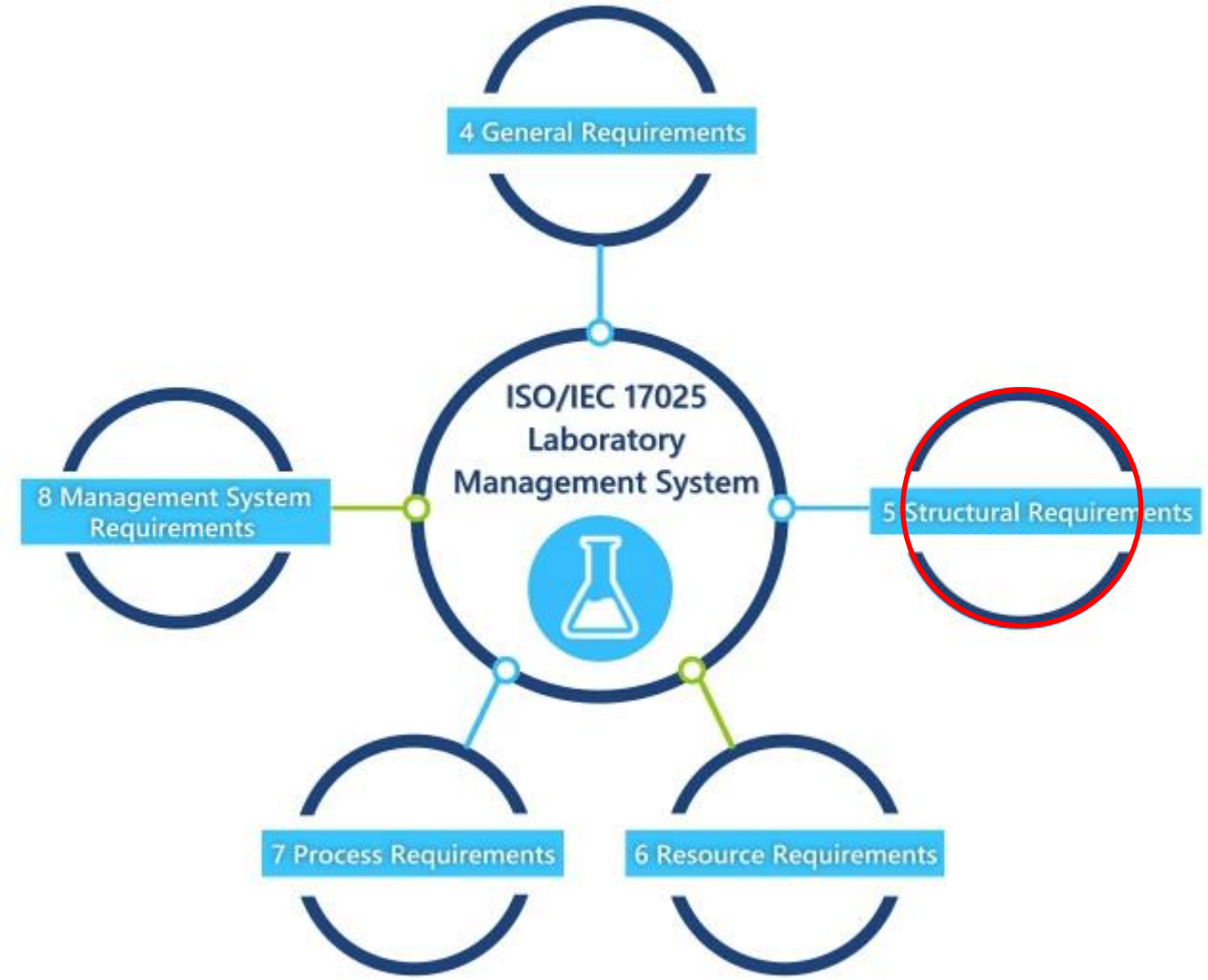
5. Structural requirements



The different sections

- Section 5: Structural Requirements. This clause represents the legal entity that defines and documents the range of laboratory activities. Additionally, it identifies the management, the laboratory activities, the organization and management structure, the responsibility, authority and interrelationships of all personnel. It defines the basic organizational components of a laboratory, its range of activities, and its commitment to an effective management system. It states that an accredited laboratory must be a legal entity or part of a legal entity, which is responsible for its testing and calibration activities. It sets management's responsibilities in an accredited laboratory and their responsibilities to customers, regulatory authorities, and organizations that provide recognition. Section 5 also defines the basic requirements for personnel, the authority given to them, and the resources needed to carry out their duties.

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5 Structural requirements

5.1 Laboratory to be legal entity or part of legal entity

5.2 Identify Laboratory management with overall responsibility

5.3 Define and document range and scope of laboratory activities. Exclude external provided activities

5.4 Cover work (calibration and or testing) at permanent facilities and at other site or mobile facilities or at a customer's facility

5 Structural requirements

5.5 The Laboratory have :

- Define the organization and management structure Managerial and technical personnel having authorities and resources to implement, maintain and improve the management system. Specify the responsibility, authority and

- Document procedures to assure the consistent application of its activities and validity of the results

5 Structural requirements

5.6 The laboratory have personnel irrespective of other responsibilities, have the authority and resources to carry out their duties

The word “quality manager” or “technical manager” technical management is removed

5.7a Ensure communication for effectiveness of system and the importance of meeting customers' and other requirements

5.7b Change management and maintain integrity of system

- N.B Include in the scope of accreditation only testing/calibration/sampling activities that is providing by utilizing its own resources.

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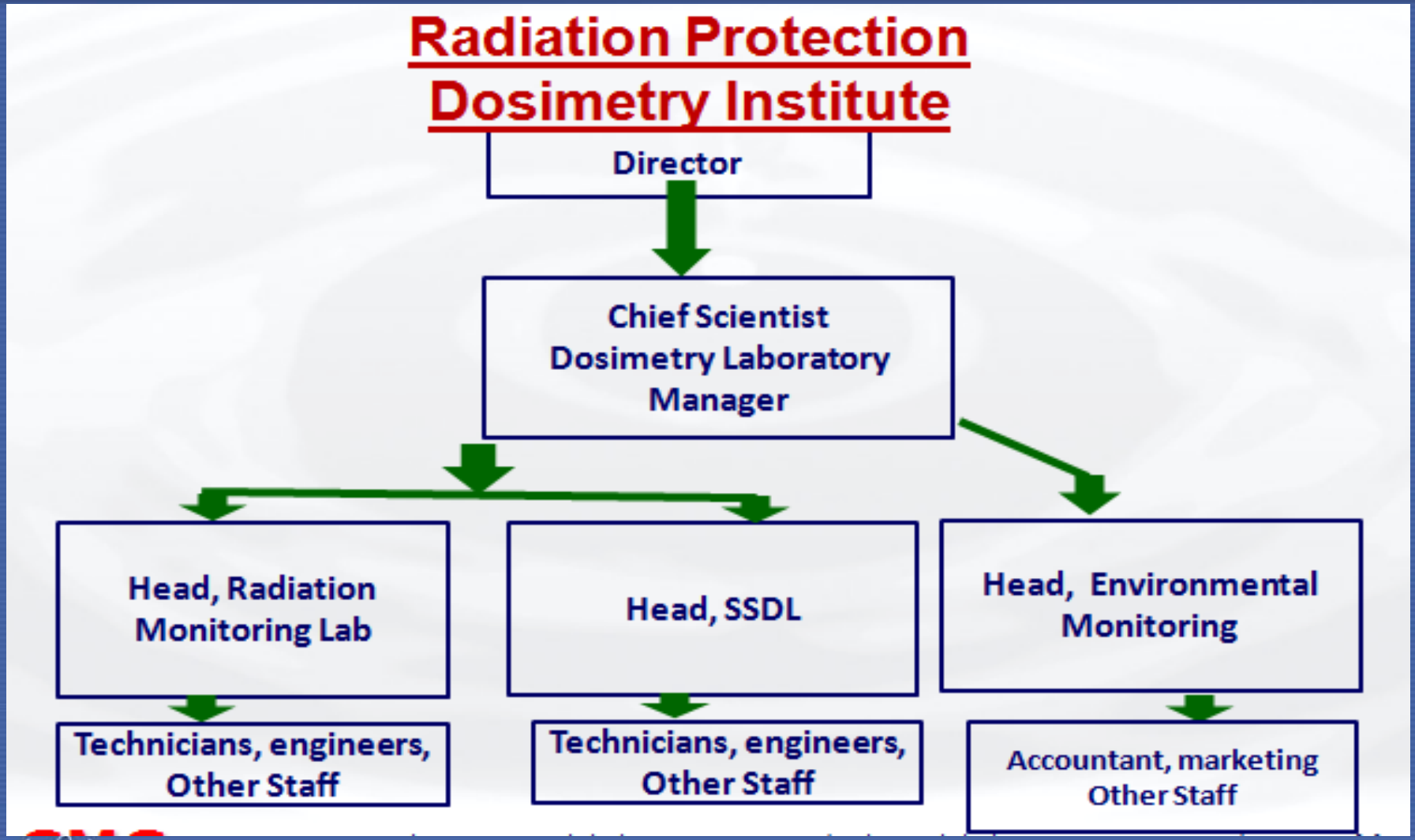
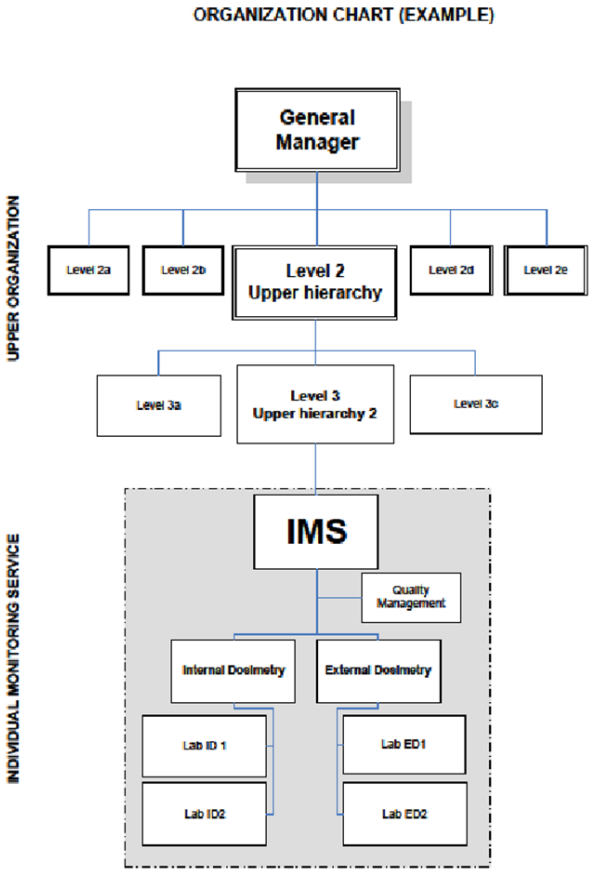
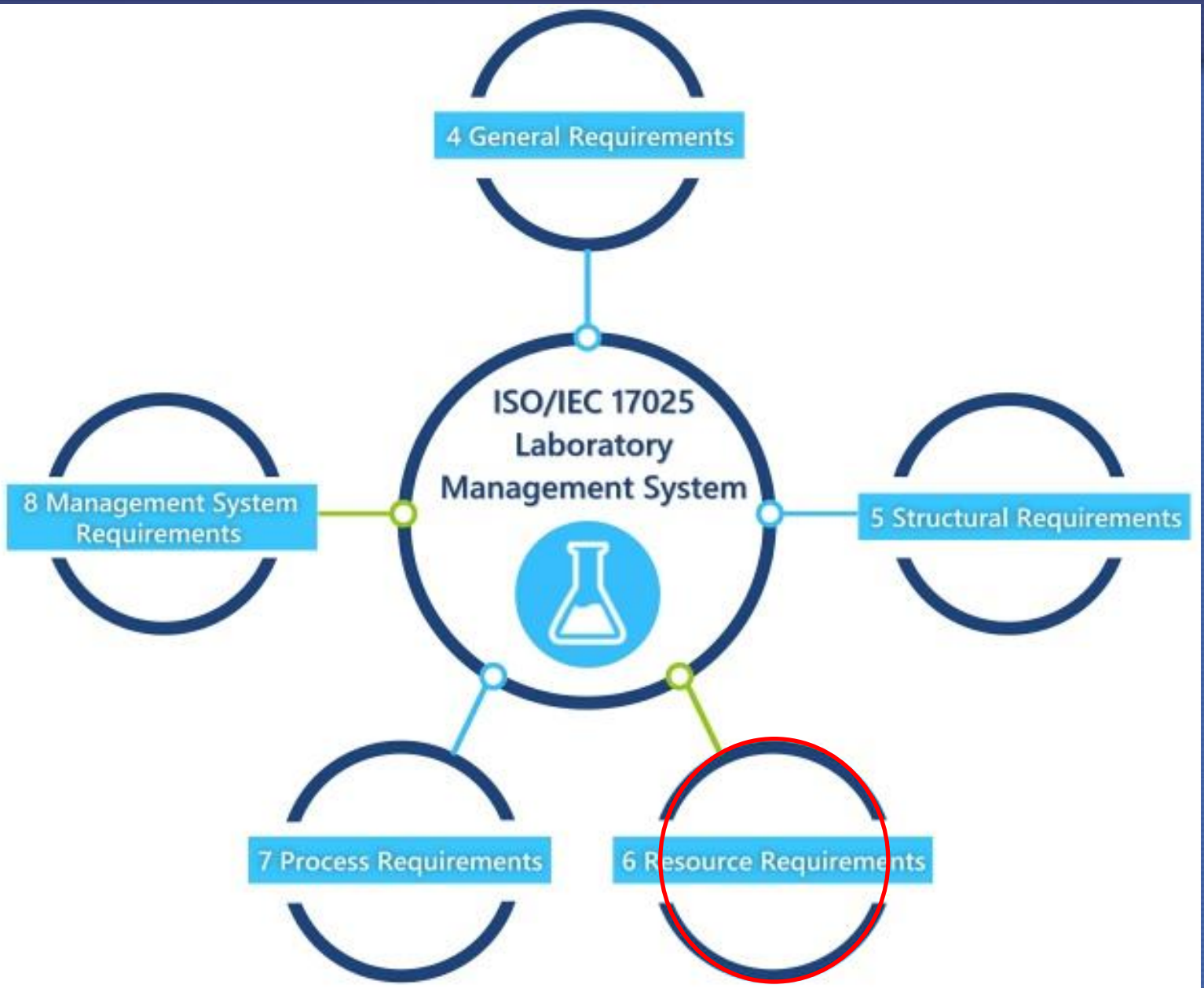
Sample Organization Chart



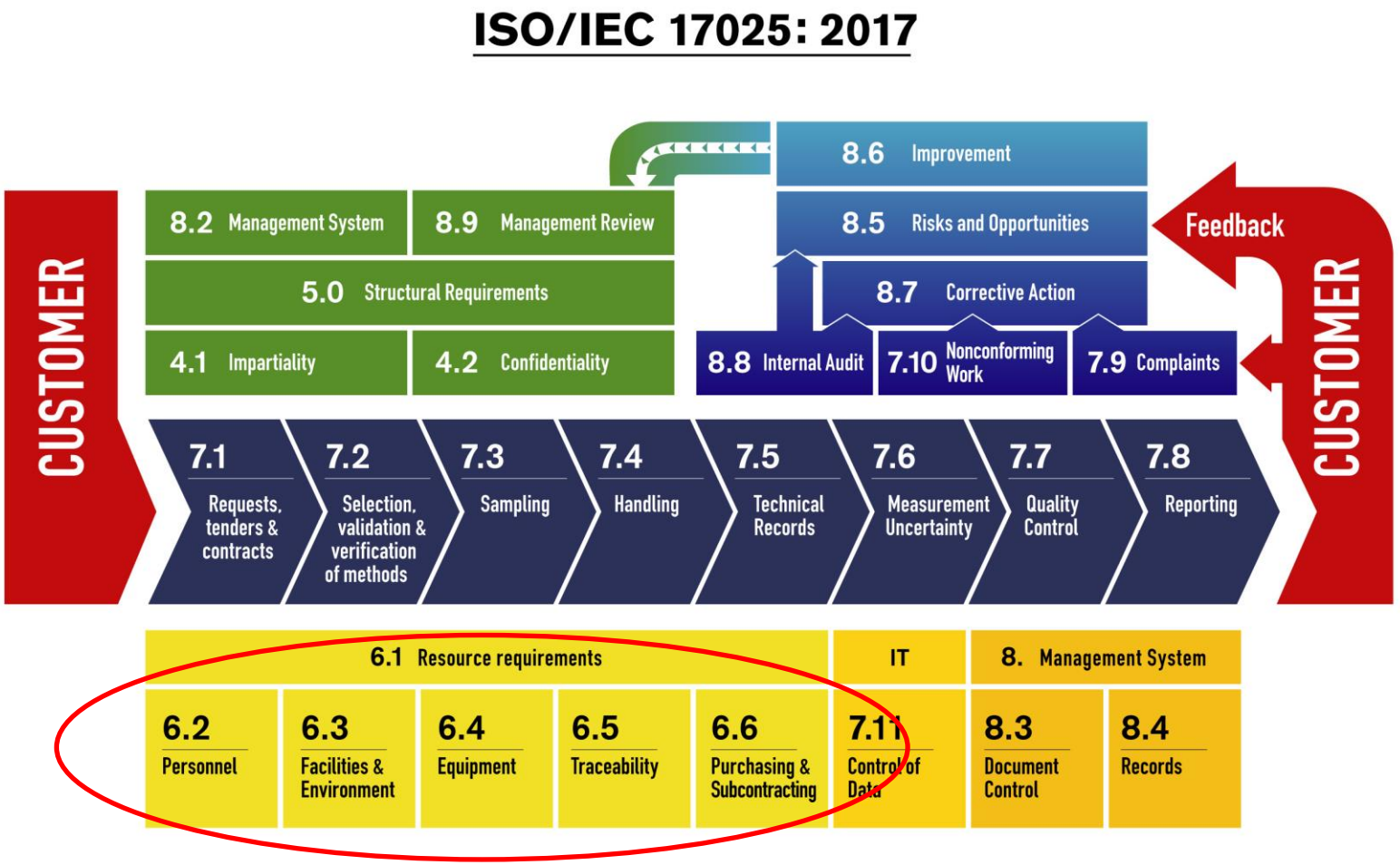
Sample Organisation Chart



Source: EURADOS Report 2020-02


4 General Requirements
ISO/IEC 17025
Laboratory
Management System
8 Management System
Requirements
5 Structural Requirements
7 Process Requirements
6 Resource Requirements

Structure


ISO/IEC 17025: 2017
8.6 Improvement
8.2 Management System
8.9 Management Review
8.5 Risks and Opportunities
Feedback
5.0 Structural Requirements
8.7 Corrective Action
CUSTOMER
4.1 Impartiality
4.2 Confidentiality
8.8 Internal Audit
7.10 Nonconforming Work
7.9 Complaints
CUSTOMER
7.1 Requests, tenders & contracts
7.2 Selection, validation & verification of methods
7.3 Sampling
7.4 Handling
7.5 Technical Records
7.6 Measurement Uncertainty
7.7 Quality Control
7.8 Reporting
6.1 Resource requirements
IT
8. Management System
6.2 Personnel
6.3 Facilities & Environment
6.4 Equipment
6.5 Traceability
6.6 Purchasing & Subcontracting
7.11 Control of Data
8.3 Document Control
8.4 Records

The different sections

- Section 6: Resource Requirements. This clause highlights the importance of the provision of the resources such as the personnel, facilities and environmental conditions, equipment, metrological traceability, and the externally provided products and services used to support the operation of the laboratory

- See separate slides

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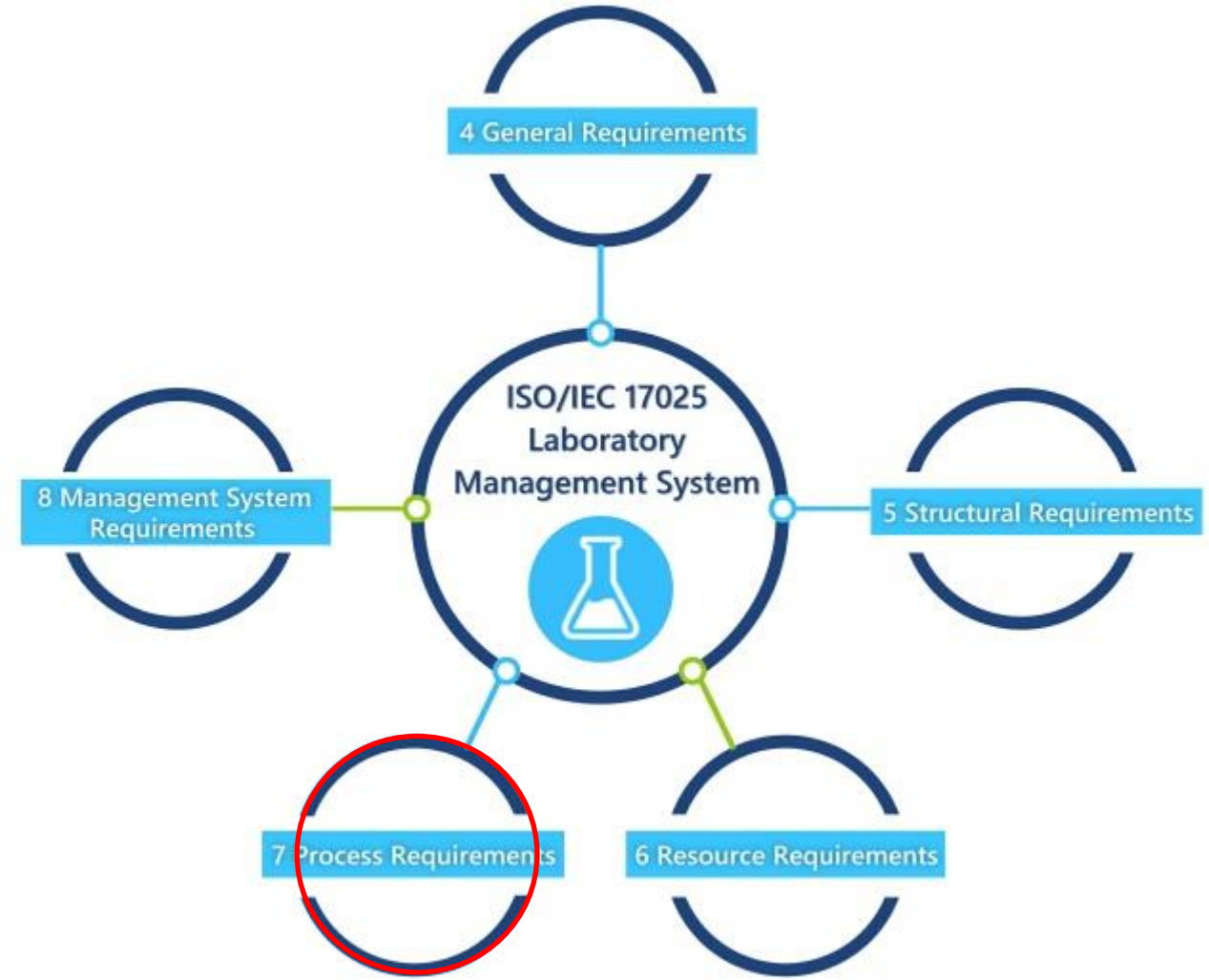
7 Process Requirements



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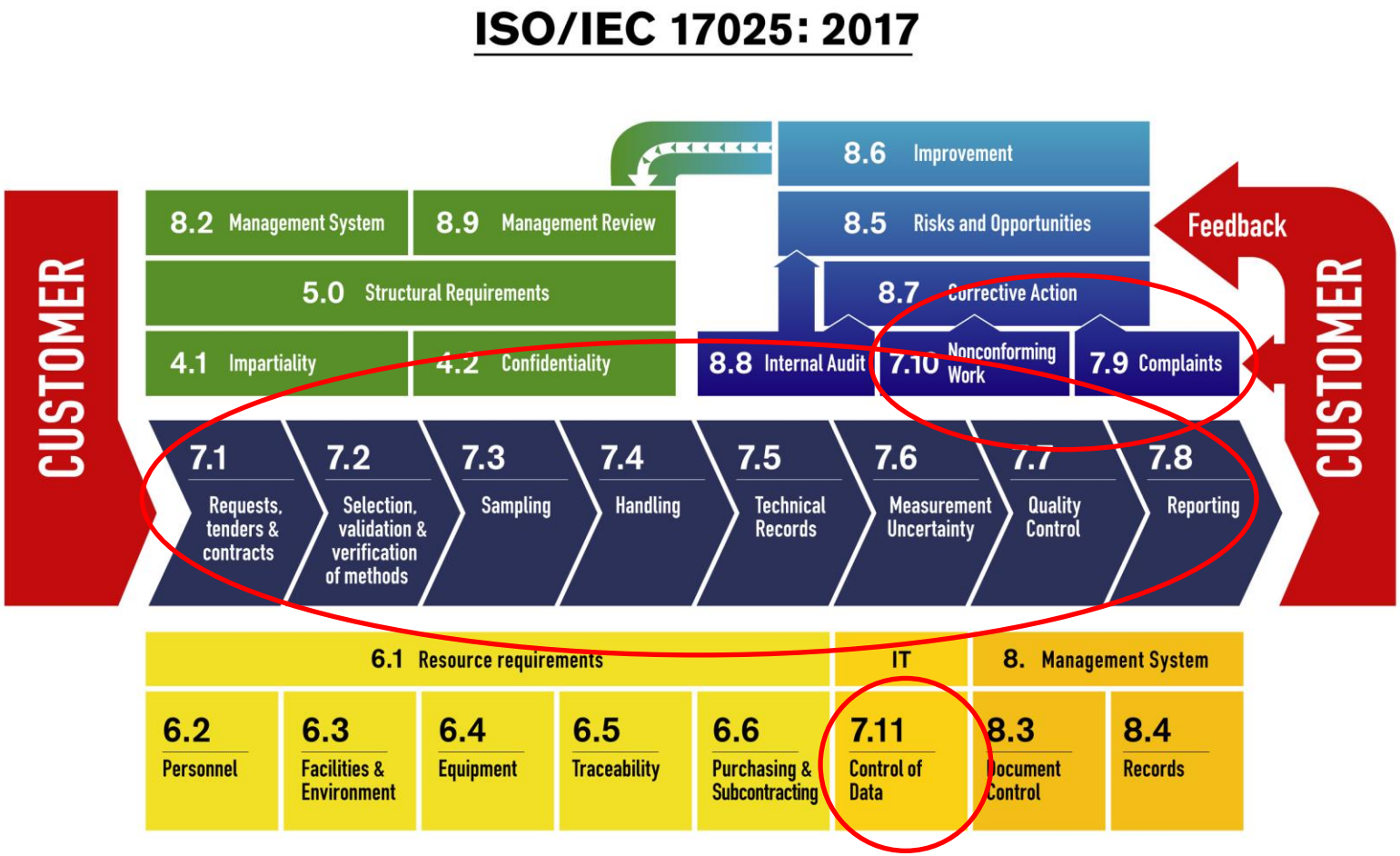
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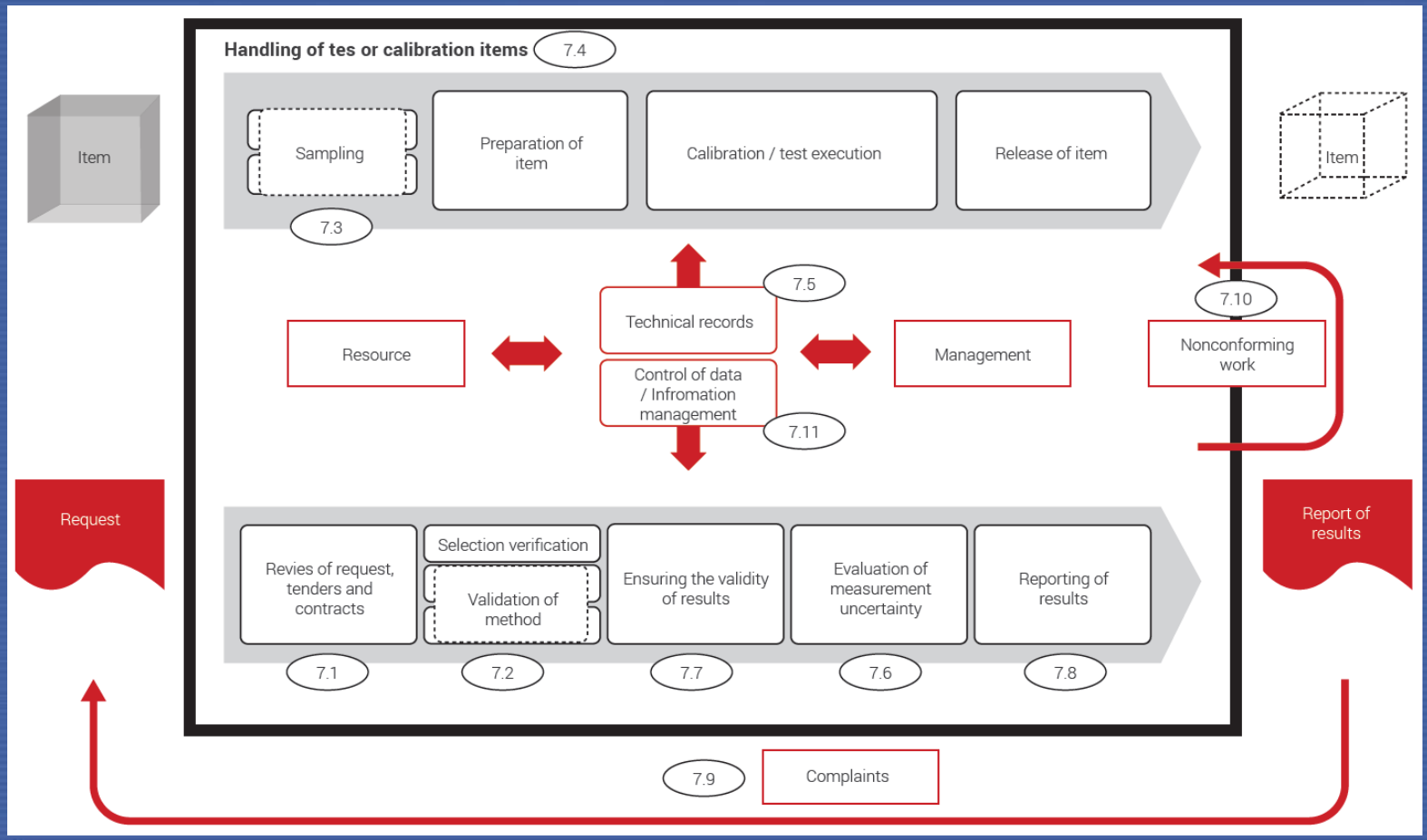

The different sections

- Section 7: Process Requirements. In this clause, it is mentioned that the process requirements are deployed as follows:
  - Review of requests, tenders, and contracts;
  - Selection, verification, and validation of methods;
  - Sampling;
  - Handling of test or calibration items;
  - Technical records;
  - Evaluation of measurement uncertainty;
  - Assuring the validity of results;
  - Reporting of results;
  - Complaints;
  - Nonconforming work;
  - Control of data – information management

- See separate slides

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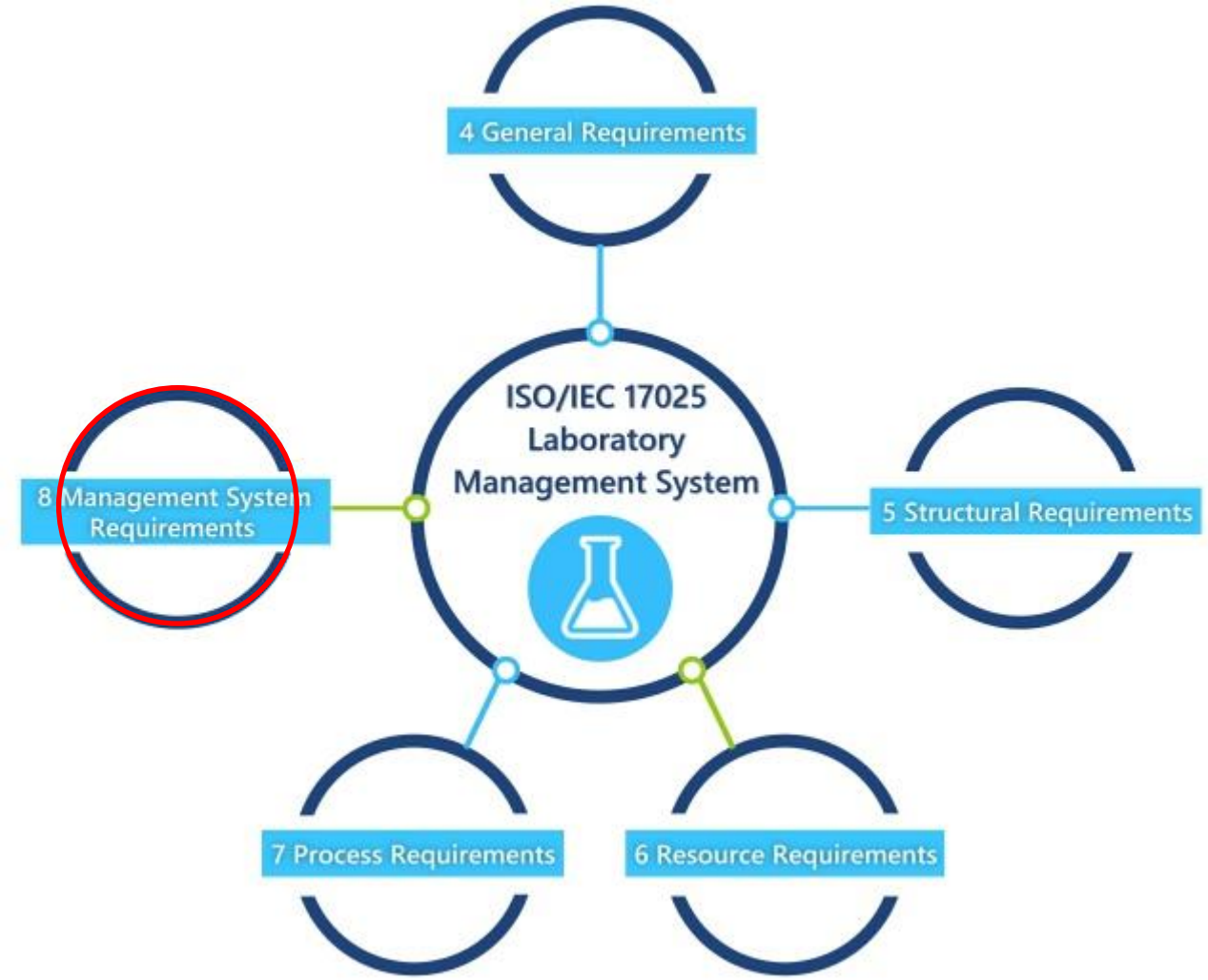
8 Management System Requirements



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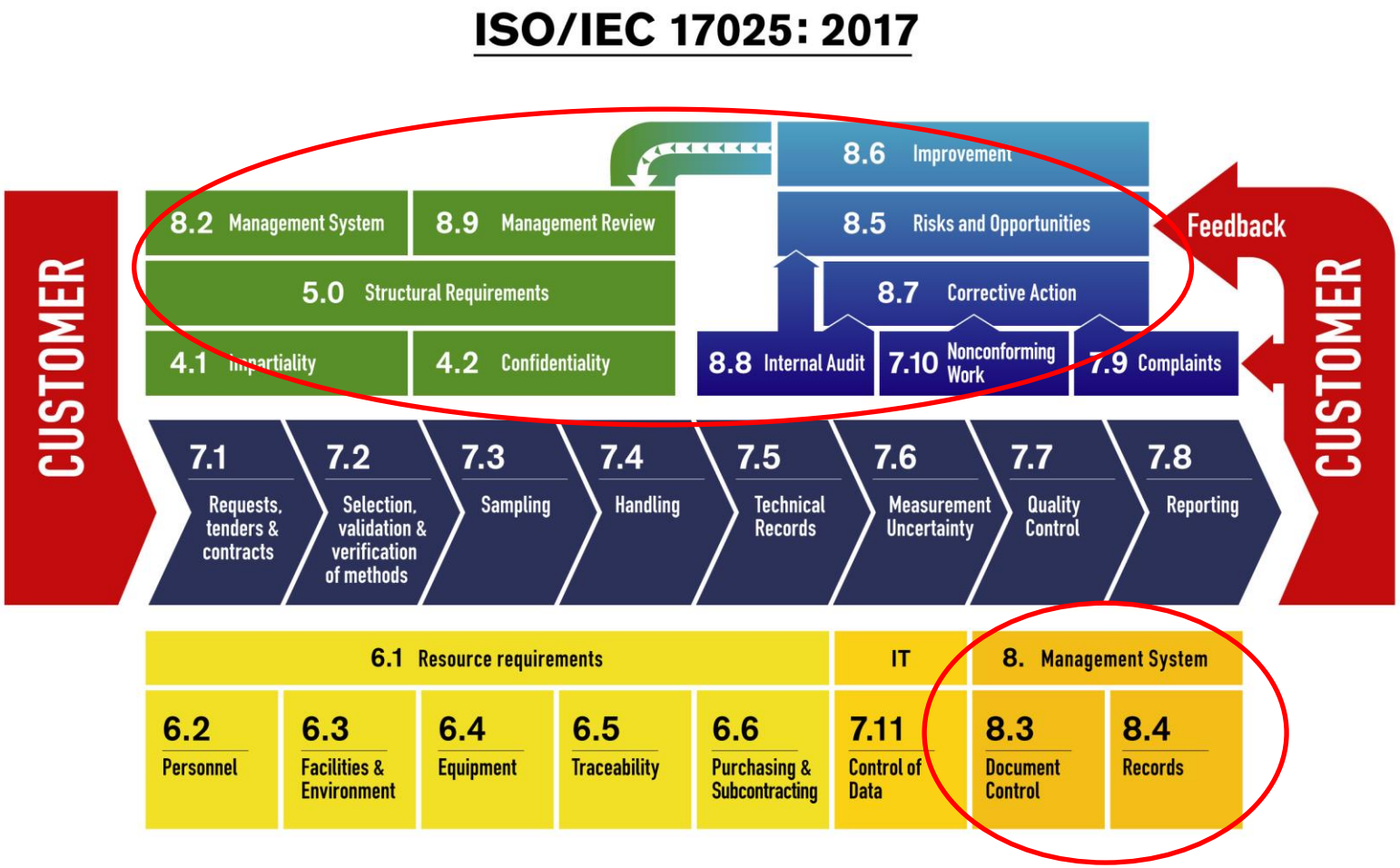
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The different sections

- Section 8: Management Systems Requirements. This section covers eight activities, including QMS documentation such as policies and objectives, control of documentation and records, addressing risks and opportunities, improvement, and corrective action.

- See specific slides

8.1 Options

Establish, document, implement and maintain a management system in accordance with option A or option B

- Option A - The laboratory is not certified to ISO 9001 but implement and address clauses 8.2 to 8.9. It lists the minimum requirements for implementation of a management system in a laboratory
- **At a minimum the laboratory addresses 8.2 – 8.9**

- Option-B- The laboratory has established and maintained the system to ISO 9001 and fulfils at least the intent of the management system section requirements 8.2 to 8.9

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8.1 Option

The requirements for documentation have been significantly reduced in clause 8. The documentation requirements related to the operation of the management system per clause 8 are:

- Management System policies and objectives (8.2.1)
- Analysis of Customer feedback (8.6.2)
- Corrective actions, non-conformities related records (8.7.3)
- Internal audit and results records (8.8.2)
- Management review input and output record (8.9.2)

There are no requirements any more for documented procedures related to management system activities referred in clause 8.

There is also no requirement for Quality Manual.